

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
20 March 2003 (20.03.2003)

PCT

(10) International Publication Number
WO 03/022252 A3

(51) International Patent Classification⁷: A61K 9/22, 9/48,
31/4422, 31/41, 31/137, 31/403, 31/55, A61P 31/18, 35/00

(21) International Application Number: PCT/CA02/01360

(22) International Filing Date:
5 September 2002 (05.09.2002)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
09/947,464 7 September 2001 (07.09.2001) US

(71) Applicant (for all designated States except US): INTEL-
LIPHARMACEUTICS CORP. [CA/CA]; 405 Britannia
Road East, Suite 106, Mississauga, Ontario L4Z 3E7 (CA).

(72) Inventors; and

(75) Inventors/Applicants (for US only): ODIDI, Isa
[CA/CA]; 200 Walmer Road, Toronto, Ontario M5R
3R7 (CA). ODIDI, Amina [CA/CA]; 200 Walmer Road,
Toronto, Ontario M5R 3R7 (CA).

(74) Agents: BARTOSZEWICZ, Lola, A. et al.; Sim &
McBurney, 330 University Avenue, 6th Floor, Toronto,
Ontario M5G 1R7 (CA).

(81) Designated States (national): AE, AG, AL, AM, AT, AU,
AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU,
CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH,
GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC,
LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW,
MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SD, SE, SG,
SI, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ,
VC, VN, YU, ZA, ZM, ZW.

(84) Designated States (regional): ARIPO patent (GH, GM,
KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW),
Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM),
European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE,
ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, SK,
TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ,
GW, ML, MR, NE, SN, TD, TG).

Published:

- with international search report
- before the expiration of the time limit for amending the
claims and to be republished in the event of receipt of
amendments

(88) Date of publication of the international search report:
17 July 2003

For two-letter codes and other abbreviations, refer to the "Guid-
ance Notes on Codes and Abbreviations" appearing at the begin-
ning of each regular issue of the PCT Gazette.

(54) Title: COMBINATORIAL TYPE (SEVERAL VEHICLES WITHIN A HOUSING) CONTROLLED RELEASE DRUG DE-
LIVERY DEVICE

(57) Abstract: The present invention is a controlled release delivery device. The device comprises more than one vehicle comprising
up to 60% by wgt active agent; up to 60% by wgt amino acid; up to 60% by wgt buffer, and up to 70% by wgt polymer. The vehicle(s)
are provided within a housing.

WO 03/022252 A3

INTERNATIONAL SEARCH REPORT

 International Application No
 PCT/CA 02/01360

A. CLASSIFICATION OF SUBJECT MATTER

 IPC 7 A61K9/22 A61K9/48 A61K31/4422 A61K31/41 A61K31/137
 A61K31/403 A61K31/55 A61P31/18 A61P35/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ, BIOSIS, MEDLINE, EMBASE

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4 940 588 A (GEOGHEGAN EDWARD J ET AL) 10 July 1990 (1990-07-10) column 2, line 60-63 column 4, line 10 -column 8, line 42 column 2, line 65,66 column 3, line 23 -column 4, line 6 column 7, line 32-34 column 7, line 43 column 7, line 58-60	1-24
X	EP 0 960 620 A (RANBAXY LAB LTD) 1 December 1999 (1999-12-01) page 3 '0011! page 2 '0004!	1-24
	-/-	

☒ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

* Special categories of cited documents:

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
- *Z* document member of the same patent family

Date of the actual completion of the international search

30 April 2003

Date of mailing of the international search report

09/05/2003

Name and mailing address of the ISA

 European Patent Office, P.B. 5818 Patentlaan 2
 NL - 2280 HV Rijswijk
 Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
 Fax (+31-70) 340-3016

Authorized officer

Baumgärtner, H

INTERNATIONAL SEARCH REPORT

Inventor's name:
 International Application No.
 PCT/CA 02/01360

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 840 329 A (BAI JANE PEI-FAN) 24 November 1998 (1998-11-24) claims 1,7 column 7, line 58-65 column 8, line 5-11	1-24
X	WO 90 11070 A (PITMAN MOORE INC) 4 October 1990 (1990-10-04) claims 1,9 page 6, line 31 page 17; example 8	1-24
Y	WO 94 28882 A (CHEN CHIH MING) 22 December 1994 (1994-12-22) page 2/last para - page 3 1st full para	1-24
Y	US 6 228 400 B1 (LEE FANG-YU ET AL) 8 May 2001 (2001-05-08) column 4, line 34 column 4, line 40-42	1-24
Y	US 5 972 389 A (SHELL JOHN W ET AL) 26 October 1999 (1999-10-26) column 5, line 64 -column 6, line 24 column 1, line 67 -column 2, line 2 column 6, line 32 column 6, line 34,35	1-24

INTERNATIONAL SEARCH REPORT

national application No.
PCT/CA 02/01360

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:

2. ☒ Claims Nos.: 1, 3, 4, 8, 11, 13, 16, 17, 18, 19-23, 24 (all in part)
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
see FURTHER INFORMATION sheet PCT/ISA/210

3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Continuation of Box I.2

Claims Nos.: 1, 3, 4, 8, 11, 13, 16, 17, 18, 19-23, 24 (all in part)

Present claims 1, 3, 4, 8, 11, 13, 16, 17, 18, 24 relate to an extremely large number of possible compounds/pharmaceutical formulations. Support within the meaning of Article 6 PCT and/or disclosure within the meaning of Article 5 PCT is to be found, however, for only a very small proportion of the compounds/pharmaceutical formulations claimed. In the present case, the claims so lack support, and the application so lacks disclosure, that a meaningful search over the whole of the claimed scope is impossible. Consequently, the search has been carried out for those parts of the claims which appear to be supported and disclosed, namely those parts relating to the compounds/pharmaceutical formulation:

vehicles (claims 1/24), cf. claim 2
active agents (claims 1/13/16/17/18/24), cf. claims 14 and 15
amino acid (claims 1/13/24) cf. description examples
buffer (claims 1/24), cf. claim 5
polymer (claims 1/24) cf. claim 6
housing (claims 1/24) cf. claim 7

The definition of the vehicle shapes (claim 8) and of the general terms as "cryoprotectant, lyoprotectant and surfactant" (claim 11) are not precise enough and does not render it possible to cover the whole range of the included meaning.

The same holds true for claims 19-23 referring to release order kinetics. It goes without saying that the definition of technical features by parameters does not provide a mean to clearly compare the claimed subject-matter vis-à-vis the prior art, thus rendering it impossible to carry out a complete search which would include any of the existing prior art having the same - implicit - features.

The applicant's attention is drawn to the fact that claims, or parts of claims, relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/CA 02/01360

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 4940588	A	10-07-1990	IE 58110 B1	14-07-1993
			AU 579415 B2	24-11-1988
			AU 4916185 A	08-05-1986
			BE 903540 A1	17-02-1986
			BE 903541 A7	17-02-1986
			CA 1268051 A1	24-04-1990
			CH 669728 A5	14-04-1989
			DE 3538429 A1	30-04-1986
			DK 495585 A	01-05-1986
			FR 2572282 A1	02-05-1986
			GB 2166651 A ,B	14-05-1986
			HK 44091 A	14-06-1991
			IT 1185831 B	18-11-1987
			JP 2820239 B2	05-11-1998
			JP 61109711 A	28-05-1986
			NL 8502951 A ,B,	16-05-1986
			SE 8505099 A	01-05-1986
			US 4952402 A	28-08-1990
			US 5354556 A	11-10-1994
			ZA 8508300 A	30-07-1986
EP 0960620	A	01-12-1999	AU 1979699 A	13-12-1999
			BR 9910723 A	12-06-2001
			CN 1237415 A	08-12-1999
			EP 0960620 A1	01-12-1999
			WO 9961022 A1	02-12-1999
			US 2002128293 A1	12-09-2002
			ZA 9810765 A	06-08-1999
US 5840329	A	24-11-1998	AU 7493398 A	08-12-1998
			WO 9851287 A1	19-11-1998
WO 9011070	A	04-10-1990	AT 90203 T	15-06-1993
			AU 634529 B2	25-02-1993
			AU 5279290 A	22-10-1990
			DE 69001898 D1	15-07-1993
			DE 69001898 T2	23-09-1993
			DK 463061 T3	12-07-1993
			EP 0463061 A1	02-01-1992
			ES 2042292 T3	01-12-1993
			JP 4504122 T	23-07-1992
			NO 913649 A	16-09-1991
			WO 9011070 A1	04-10-1990
			US 5219572 A	15-06-1993
WO 9428882	A	22-12-1994	US 5260068 A	09-11-1993
			AU 4643493 A	03-01-1995
			EP 0701437 A1	20-03-1996
			WO 9428882 A1	22-12-1994
			US 5508040 A	16-04-1996
US 6228400	B1	08-05-2001	AU 3089201 A	31-07-2001
			CN 1358089 T	10-07-2002
			EP 1185254 A2	13-03-2002
			WO 0152816 A2	26-07-2001
US 5972389	A	26-10-1999	AU 741760 B2	06-12-2001
			AU 4428097 A	14-04-1998

INTERNATIONAL SEARCH REPORT

Information on patent family members

In ———— national Application No

PCT/CA 02/01360

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 5972389	A	EP 0941071 A1	15-09-1999
		JP 2001500879 T	23-01-2001
		KR 2000048500 A	25-07-2000
		NO 991341 A	19-05-1999
		WO 9811879 A1	26-03-1998